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REMARKS/ARGUMENTS

Applicant respectfully requests that the above application be reconsidered in view of the above amendments and the following remarks. Claims 1-20 are currently pending.

Claims 4 and 15 have been amended to correct typographical errors.

Claim 5 has been amended to further specify the shape of the collar, as disclosed in paragraph [0025] of the specification.

Claims 1, 9, and 14 have been amended to specify that the flexible domes have a height above the surface of the band of from about 0.3 to about 3 mm. Support for this amendment is found at paragraphs [0028] and [0040] of the specification.

Claims 1, 9, and 14 have also been amended to specify that when the flexible domes compress against the tube and grip it, they do so without significantly compressing the tube and restricting air flow. Support for this amendment is found at paragraphs [0029] and [0041] of the specification, as well as in FIG. 6.

No new matter is introduced by the above amendments, and it is requested that they be entered.

A. Response to Objections to the Drawings Under 37 CFR 1.83(a)

The drawings have been objected to under 37 CFR 1.83(a). It is noted that the drawings must show every feature of the invention specified in the claims. The Examiner has stated that the feature "the endotracheal tube is closer to the skin between the patient's nose and upper lip proximally than distally" in Claim 5 must be shown or canceled from the claim.

In response thereto, Claim 5 has been amended to specify that the collar is shaped so that it holds the endotracheal tube at an angle relative to the skin between the patient's nose and upper lip whereby the tube is closer to the skin proximally than it is distally, as disclosed in paragraph [0025] of the specification. This feature is shown in FIG. 3, so no amendment to the drawings is necessary. Accordingly, reconsideration and withdrawal of the objection to the drawings is requested.

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B. Response to Rejection of Claims 1, 4, 5, 9, 12, and 13 under 35 USC 102(b) as Anticipated by U.S. Patent 4,516,293 (Beran)

Claims 1, 4, 5, 9, 12, and 13 have all been rejected under 35 USC 102(b) as anticipated by U.S. Patent 4,516,293 (Beran).

1. The '293 reference is cited as disclosing an adjustable collar (10) for a nasal or oral endotracheal tube, which includes: a smooth first surface (14) for contacting the skin of a patient using the endotracheal tube; a support section (26) attached to the first surface (14); and a band (28) attached to the support section (26) comprising flexible domes (62) that compress against the tube (12) and grip it when the collar is secured around the tube (Fig. 4).

2. Regarding Claim 4, it is said that the '293 reference discloses the collar for use with a nasal endotracheal tube, where the collar is tapered in the region where it contacts the endotracheal tube.

3. Regarding Claim 5, it is said that the '293 reference discloses that the collar is shaped so that the endotracheal tube is closer to the skin between the patient's nose and upper lip proximally than distally.

4. Regarding Claim 9, it is said that the '293 reference discloses an adjustable collar (10) comprising: a smooth first surface (14) for contacting the skin of the patient; a support section (26) attached to the first surface (14), and a band (28) attached to the support section (26) comprising flexible domes (62) that compress against the tube (12) and grip it when the collar is secured around the tube (12, Fig. 4); and lateral extensions (18-21) from the collar for securing the collar to the head of the patient.

5. Regarding Claim 12, it is said that the '293 reference discloses that the lateral extensions have a bi-lobed appearance.

6. Regarding Claim 13, it is said that the '293 reference discloses that the lateral extensions have a smooth surface that contact the patient's skin.

Applicant respectfully traverses this rejection.

In the present invention, flexible domes compress against and grip the endotracheal tube when the collar is secured around the tube. As noted in paragraphs [0029] and [0041] of Applicant's specification, when the flexible domes are pulled tight against the tube, the flexible

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domes compress and grip the tube without significantly compressing the tube and restricting airflow.

In contrast, as stated in the '293 reference at col. 2, lines 17-24:

"The holding structure is arranged so that the tube is pressed to slightly oval shape at the region where it is engaged by the holder. That is augmented, or even replaced, by projections that extend from the holder into engagement with the exterior wall of the tube. In preferred form those projections do not pierce the tube wall, but merely distort its shape in small degree." (emphasis added)

Unlike the apparently rigid projections in the '293 reference, the flexible domes of Applicants' invention do not distort or significantly compress the tube. This feature is best seen in FIG. 6 of the specification, where the flexible domes shown in FIG. 5 are compressed against the tube as the collar is secured around the tube. The tube is not distorted or compressed. This is contrasted with FIG. 4 of the '293 reference, where the tube is distorted by the projections. As noted above in the quote from col. 2, the projections of the '293 reference can even pierce the tube wall, but preferably merely distort the shape of the tube. The '293 reference further discloses that its projections cause deformation of the tube wall at col. 5, lines 63, 65 and 68, and at col. 6, lines 3 and 21. In light of this distinction, the '293 reference does not anticipate Applicant's claimed invention. Instead, the '293 reference teaches away from Applicant's invention by disclosing a design which distorts, deforms, and may even pierce the tube.

Moreover, Applicant's Claims 1, 9, and 13 have been amended to specify that the domes have a height above the surface of the band of from about 0.3 to about 3 mm. The '293 reference discloses that the projections which restrain the tube are "small" (see col. 5, line 64), but does not quantify the size of these projections. However, they appear in FIGS. 2-5 to be much smaller than the tube. Applicant's flexible domes are larger, e.g., see FIGS. 5-6 of the specification. This further distinguishes the '293 reference.

For the foregoing reasons, Applicant submits that Claims 1, 4, 5, 9, 12, and 13 are not anticipated by the '293 reference. Accordingly, reconsideration and withdrawal of the rejection under 35 USC 102(b) is requested.

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C. Response to Rejection of Claims 2, 3, 6-8, 10, 11, and 14-20 under 35 USC 103(a) as Unpatentable Over U.S. Patent 4,516,293 (Beran)

Claims 2, 3, 6-8, 10, 11, and 14-20 have been rejected under 35 USC 103(a) as being unpatentable over U.S. Patent 4,516,293 (Beran).

1. It is stated that the difference between the '293 reference and Claim 2 is that the collar is being made of a semi-rigid, non-irritating plastic material. It is stated that it would have been obvious to have the collar made of a semi-rigid, non-irritating plastic material. Claims 3, 6, and 10 are also rejected on this basis.
2. Regarding Claims 7 and 11, it is stated that the '293 reference discloses that a retainer strip underlies the domes (44).
3. Regarding Claim 8, it is stated that the '293 reference discloses that the strip comprises a lock at one end (32) and a belt at the other end.
4. Regarding Claim 14, it is stated that the '293 reference discloses holders that include an adhesive surface or other attachment means including straps and hook and fabric arrangements, and that it would have been obvious to substitute the adhesive for strap attachment means as disclosed by the '293 reference.
5. Regarding Claim 15, it is said that the '293 reference discloses that hook and fabric arrangements are known, and that it would have been obvious to have at least one strap of hook and loop refastenable material, as such material is known in the art.
6. Regarding Claim 16, it is said that it would be inherent that at least one lateral strap connects the at least one strap connected to the lateral extensions.
7. Regarding Claim 17, the Examiner refers to the rejection of Claim 2 above.
8. Regarding Claim 18, the Examiner states that the '293 reference discloses that the lateral extensions have a bi-lobed appearance.
9. Regarding Claim 19, it is said that the '293 reference discloses that a retainer strip (44) underlies the domes (62).
10. Regarding Claim 20, while the '293 reference does not disclose two straps, it is stated that it would have been obvious to have two straps.

Applicant respectfully traverses this rejection.

As discussed under Part C above, in the present invention, flexible domes compress against and grip the endotracheal tube when the collar is secured around the tube. As noted in

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paragraphs [0029] and [0041] of Applicant's specification, when the flexible domes are pulled tight against the tube, the flexible domes compress and grip the tube without significantly compressing the tube and restricting airflow.

In contrast, as stated in the '293 reference at col. 2, lines 17-24:

"The holding structure is arranged so that the tube is pressed to slightly oval shape at the region where it is engaged by the holder. That is augmented, or even replaced, by projections that extend from the holder into engagement with the exterior wall of the tube. In preferred form those projections do not pierce the tube wall, but merely distort its shape in small degree." (emphasis added)

Unlike the apparently rigid projections in the '293 reference, the flexible domes of Applicant's invention do not distort or significantly compress the tube. This feature is best seen in FIG. 6 of the specification, where the flexible domes shown in FIG. 5 are compressed against the tube as the collar is secured around the tube. The tube is not distorted or compressed. This is contrasted with FIG. 4 of the '293 reference, where the tube is distorted by the projections. As noted above in the quote from col. 2, the projections of the '293 reference can even pierce the tube wall, but preferably merely distort the shape of the tube. The '293 reference further discloses that its projections cause deformation of the tube wall at col. 5, lines 63, 65 and 68, and at col. 6, lines 3 and 21. In light of this distinction, the '293 reference does not render obvious Applicant's claimed invention. Instead, the '293 reference teaches away from Applicant's invention by disclosing a design which distorts, deforms, and may even pierce the tube.

Moreover, Applicant's Claims 1, 9, and 13 have been amended to specify that the domes have a height above the surface of the band of from about 0.3 to about 3 mm. The '293 reference discloses that the projections which restrain the tube are "small" (see col. 5, line 64), but does not quantify the size of these projections. However, they appear in FIGS. 2-5 to be much smaller than the tube. Applicant's flexible domes are larger, e.g., see FIGS. 5-6 of the specification. This further distinguishes the '293 reference.

For the foregoing reasons, Applicant submits that Claims 2, 3, 6-8, 10, 11, and 14-20 are patentable over the '293 reference.

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D. Conclusion

It is believed that the above represents a complete response to the Examiner's objection and rejections and places the application in condition for allowance. Accordingly, reconsideration and allowance of Claims 1-20 are respectfully requested.

Applicant would appreciate the courtesy of a telephone call should the Examiner have any questions or comments with respect to this response.

Respectfully submitted,

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